

Claim Rejection -- 35 U.S.C. §103

The obviousness rejection of claims 1, 2 and 5-17 over Lewis (Methods in Enzymology, Vol. XIII, pp. 615-616, 1969) in view of Lowenstein (US 3,764,692) was maintained. Applicants respectfully traverse the rejection.

The teachings of Lewis and Lowenstein are summarized in the Response filed on July 6, 1999.

Lewis differs from the claimed process in at least four ways:

- (1) Lewis treats an **aqueous extract** of *Garcinia* fruit rind with alcohol, but the claimed process directly treats *Garcinia* fruit with alcohol;
- (2) Lewis treats an **aqueous filtrate** containing alcohol with KOH (see step 6 in the above summary), but the claimed process treats an **alcohol extract** with KOH;
- (3) after adding KOH, Lewis obtained an oily liquid which was washed with alcohol (**no refluxing**; see p. 616, line 1), but in the claimed process, after adding KOH, **reflux** was performed to obtain a precipitate of potassium hydroxy citrate; and
- (4) the first half of Lewis' process makes the potassium salt of hydroxycitric acid as a heavy oily liquid of low purity requiring repeated washing with alcohol to obtain a semisolid (see Lewis, p. 615, lines 15-17; p. 616, lines 1-7), but the claimed process makes the potassium salt of hydroxycitric acid as a precipitate of high purity requiring only one washing with alcohol.

The Office Action attempts to rely on Lowenstein to cure the differences between Lewis and the claimed process. But Lowenstein merely teaches that the free acid form

of hydroxycitric acid may be obtained from the lactone form of hydroxycitric acid by treatment with KOH followed by acidification (see column 1, lines 35-39).

Regarding difference (1), the Office Action states that this difference is obvious because the Patent Office assumed that Garcinia fruits contain some water, so the Patent Office asserted that "the claimed step is nothing more than the optimization of Lewis' process. Furthermore, the Examiner feels that no patentably distinct step is involved in that procedure." Applicants respectfully disagree.

Applicants submit that directly treating Garcinia fruit with alcohol, as in the claimed process, would not have been obtained by an optimization of Lewis' process. Treating the aqueous extract of Garcinia fruit rind with alcohol is totally different from treating the Garcinia fruit directly with alcohol. In the claimed process, treating Garcinia fruit directly with alcohol can extract all alcohol-soluble substances in the fruit. In contrast, treating the aqueous extract of Garcinia fruit rind with alcohol in Lewis' process is to extract only water-soluble substances in the fruit rind which are also alcohol soluble. It is not as simple as a mere optimization by replacing the step of Lewis of treating the aqueous extract of the fruit rind with alcohol, with directly treating the fruit with alcohol as in the claimed process. Applicants respectfully request that the Patent Office explain where the motivation comes from in modifying Lewis' process by directly extracting the fruit with alcohol, instead of extracting the fruit rind with water first and then extracting the aqueous extract with alcohol. By failing to provide a motivation for the modification of the prior art process to arrive at the claimed process and by simply concluding that the claimed process was obvious, the Patent Office appears to have engaged in hindsight analysis prohibited by case law.

Applicants submit that the motivation is to not modify Lewis' process because one of ordinary skill in the art would have known that hydroxy citric acid is very water soluble and Lewis discloses that hydroxy citric acid is the major organic acid present in the fruit rind of *Garcinia* (see page 615, Footnote 10). Thus, treating the fruit rind first with water, followed by a treatment with alcohol to remove a pectinous material as in Lewis's process (see p. 615, the 3rd and 4th lines from the bottom), would have reasonably been expected to extract the most amount of hydroxy citric acid. There would have been no motivation to replace the procedures in Lewis' process by directly extracting the fruit with alcohol.

Additionally, due to purity concerns, there would have been no motivation to replace the steps of Lewis of first extracting the fruit rind with water and then extracting the aqueous extract with alcohol. By first extracting the fruit rind with water in Lewis' process, Lewis was eliminating other substances in the fruit rind not soluble in water or having a very low solubility in water. There would have been no motivation to replace the steps of Lewis with a step of directly extracting the *Garcinia* fruit with alcohol because extracting the *Garcinia* fruit with alcohol could pick up substances not soluble in water or having a very low solubility in water. Thus, one of ordinary skill in the art would have reasonably expected that directly extracting the fruit with alcohol, as in the claimed process, could require additional steps to purify the hydroxy citric acid. This reasonable expectation would drive this artisan away from modifying Lewis' process to directly extract the fruit with alcohol as in the claimed process. Therefore, difference (1) would not have been obvious.

Furthermore, the mere fact that Garcinia fruit contains some water does not make directly extracting the fruit with alcohol as in the claimed process equivalent to extracting (in an autoclave) the fruit rind with water first and then extracting the aqueous extract with alcohol as in Lewis' process. The little bit of water in the Garcinia fruit is not the same as an aqueous extract of the fruit rind made in an autoclave using 600 ml of water in Lewis' process (see p. 615, the 8th and 9th lines from the bottom).

The Office Action states that difference (2) is obvious because what the inventors did was "merely reversing the order of steps in a multi-step process". The Office Action acknowledges that, in Lewis' process, the aqueous supernatant (presumably the Office Action is referring to the aqueous filtrate in the second to the last line of p. 615 of Lewis) is treated with KOH to obtain an oily liquid and then the KOH is removed before a mixture (presumably the Office Action is referring to the heavy oily liquid in the last line of p. 615 of Lewis) is washed with ethanol. Applicants note that the claimed process simply treats an alcohol extract with KOH (see step (e) of claim 1). Applicants submit that "merely reversing the order of steps" in Lewis' process, as alleged by the Office Action, would not arrive at step (e) of claim 1. This is because reversing Lewis' steps of (1) treating the aqueous filtrate with KOH, (2) removing the KOH to obtain an oily liquid, and (3) washing the oily liquid with ethanol (the first three lines of p. 616 of Lewis) would not arrive at step (e) of treating the alcohol extract with KOH to obtain a treated extract in claim 1.

Regarding difference (3), the allegations by the Office Action (either the optimization of Lewis' process or "merely reversing the order of steps") would not have resulted in the claimed process because Lewis provides no teaching or suggestion of

refluxing the extract after the addition of KOH. The optimization of Lewis' process or "merely reversing the order of steps" in Lewis' process would have result in the step of refluxing the alcohol extract after the addition of KOH as required in the claimed process.

Concerning difference (4) described above, the claimed process has an unexpected advantage of yielding potassium hydroxy citric acid at a higher purity than Lewis' process. The process of Lewis would require washing with alcohol three times. In contrast, the claimed process is simpler.

Another advantage of the claimed process is that the claimed process would obtain a highly stable form of hydroxy citric acid, i.e. non-lactone form of hydroxy citric acid. Please refer to pages 30-31 of the present specification which shows that the potassium hydroxy citric acid obtained by the claimed process was found to be stable at high temperature and high humidity for a minimum of 90 days. The potassium hydroxy citric acid obtained by the claimed process would be expected to be stable for about 5 years under normal storage conditions.

Withdrawal of the obviousness rejection of claims 1, 2 and 5-17 is requested.

Conclusion

With the above reasoning, applicants respectfully submit that the application is in a condition for allowance.

In case this paper is not timely filed, the undersigned hereby petitions for an appropriate extension of time. In the event that any fees are due in connection with this paper, please charge our Deposit Account No. 01-2300.

Respectfully submitted,
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